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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,122

08/18/2006

Naomi Yamakawa

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EXAMINER

STEELE, AMBER D

ART UNIT

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,122	Applicant(s) YAMAKAWA, NAOMI	
	Examiner AMBER D. STEELE	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/08; 12/5/06; 9/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-11 were originally filed on August 18, 2006.

The preliminary amendment received on August 18, 2006 amended claims 5-7 and added new claims 12-13.

Claims 1-13 are currently pending.

Claim 10 is currently under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group III (claim 10) in the reply filed on February 12, 2009 is acknowledged. The traversal is on the ground(s) that the method of Barany et al. differs from the claimed invention because (1) the disclosed method of Barany et al. seeks to detect nucleotide sequence differences, but not base modifications such as methylation and (2) Barany et al. utilized oligos rather than base-specific antibodies. This is not found persuasive because the common technical feature linking all of the inventions of Groups I-IV or even of Groups I-III is "a library of DNA fragments having cohesive ends and modified bases". For example, the DNA array of Group II does not require base-specific antibodies. In addition, while applicants provide a species of modified base at paragraph 28 of the specification (i.e. methylated cytosine) a definition for "modified base" is not present in the originally filed specification. Therefore, the broadest reasonable interpretation of the term is utilized which includes any modification of a base in a nucleotide sequence including a mutation, substitution, etc.

The requirement is still deemed proper and is therefore made FINAL.

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3. Claims 1-9 and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 12, 2009.

Priority

4. The present application claims status as a 371 of PCT/JP2005/002490 filed February 17, 2005.

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on February 20, 2004. It is noted, however, that applicant has not filed a certified copy of the 2004-044759 application as required by 35 U.S.C. 119(b). A translation may also be required to fully benefit from the foreign priority date.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on May 13, 2008; December 5, 2006; and September 25, 2006 are being considered by the examiner. Only the English language abstracts were considered for the non-English language foreign documents.

7. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and

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any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a). Only references in the search report that are listed separately on the IDS and copies provided if necessary are considered.

Drawings

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference number 1a in Figure 6 was not described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR

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1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 59.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Invention as Claimed

11. A method of analyzing a modification in a DNA to be assayed characterized by comprising the steps of (1) preparing a mixture of DNA fragments in which a modified base or a base is exposed from the DNA to be assayed, (2) bringing the mixture of DNA fragments obtained in the step (1) into contact with an antibody specific to the modified base or the base and separating the mixture into a group consisting of DNA fragments which form an immunocomplex with the antibody and another group consisting of DNA fragments which do not react with the antibody or a group consisting of DNA fragments showing a high affinity for the antibody and another group consisting of DNA fragments showing a low affinity for the antibody and (3) analyzing all or part of DNA fragments contained in each of the DNA fragments groups with a DNA array and variations thereof.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by Grigg et al. U.S.

2004/0086944 published May 6, 2004.

For present claim 10, Grigg et al. teach methods comprising (a) treating a sample containing DNA with an agent that modifies unmethylated cytosine (i.e. preparing a mixture of DNA fragments), (b) providing to the treated sample a detector ligand capable of binding to a target region of DNA and allowing a sufficient time for a detector ligand to bind a target DNA (i.e. bringing the mixture of DNA fragments into contact with an antibody specific to the modified base), and (c) utilizing a DNA array (please refer to the entire specification particularly paragraphs 12-47; claims 1, 12, 20, 42, 56-60, 64, 75, 88-93, 97).

Therefore, the disclosure of Grigg et al. anticipates the presently claimed method.

14. Claim 10 is rejected under 35 U.S.C. 102 (b) or 102(e) as being anticipated by Martinssen et al. U.S. Patent 7,186,512 (effective filing date of June 26, 2002; 102(e)) and previously published as U.S. 2004/0132048 on July 8, 2004 (102(b)).

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For present claim 10, Martienssen et al. teach methods for determining the methylation profile of individuals comprising (a) providing a uniformly-sized population of randomly cleaved or sheared DNA from a cell, tissue, or organism wherein the DNA comprises a first portion and a second portion and each portion comprises methylated and unmethylated nucleotides, (b) separating the portions into a methylated DNA subportion and an unmethylated DNA subportion via antibodies specific for methylated nucleic acids, and (c) utilizing DNA arrays (please refer to the entire specification particularly columns 1-7, 10-11; Example 4; claims 1, 4, 8-9).

Therefore, the disclosure of Martienssen et al. anticipates the presently claimed method.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639

April 6, 2009